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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Re: ALDARA™

FDA Docket No. 97E-0269


#15

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,238,944. The application was filed on April 24, 1997, under 35 U.S.C. § 156.

The patent claims a product, ALDARA™ (Imiquimod) that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act and a method of use of said product. U.S. Patent No. 4,689,338 also claims ALDARA™ (Imiquimod) and a method of use of ALDARA™ and an application for patent term extension of U.S. Patent No. 4,689,338 based upon the regulatory review period of Imiquimod has also been filed. Subject to final review, U.S. Patent No. 5,238,944 is considered to be eligible for patent term restoration, if elected. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Telephone inquiries regarding this matter should be directed to the undersigned at (703)306-3159.


Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ted K. Ringsred
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